

AUG 23 2000

K001943



## Sangui BioTech, Inc.

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Santa Ana, California 92705 USA  
714-429-7807 (Voice)  
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### SECTION 10:

### 510 (k) SUMMARY

Name of Contact Person:

John J. Kiang  
Business and Product Development Consultant [Exclusive to Sangui BioTech, Inc.]

Name of Proposed Device: Sangui BioTech, Inc. ChronAlco I.D.™ CDT (Carbohydrate Deficient Transferrin) Assay

Common name of the device: CDT (Carbohydrate Deficient Transferrin) Assay

☐ Classification name: Device: Gamma-glutamyl transpeptidase and isoenzymes test systems

Name of Predicate Device: %CDT TIA (Turbidimetric Immunoassay) by Axis Biochemical ASA, a division of Axis/Shields Diagnostics (a U.K. Corporation), Oslo, Norway. Distributed by Bio Rad Laboratories. Catalog Numbers: 194-5301, 194-5303 and 194-5305.

Description of the proposed device: The ChronAlco I.D.™ CDT Test consists of disposable ion-exchange columns with all the reagents for the chromatography and subsequent turbidimetric Immunoassay of CDT (Carbohydrate Deficient Transferrin) in serum.

Intended Use of the proposed device: The intended use of this product is the quantitative measurement of CDT (Carbohydrate Deficient Transferrin) in human serum. The ChronAlco I.D.™ CDT Test measures the CDT simultaneously with the total transferrin so that the result can be expressed as a relative ratio, i.e. %CDT or CDT as a percentage of the total transferrin. %CDT is used as a tool to identify possible chronic heavy alcohol consumption, which is indicated by %CDT values above the cutoff level of 2.7%.

Substantial Equivalency:

A total of one hundred sixteen (116) serum samples were analyzed using both methods. The correlation is excellent according to Pearson's correlation coefficient R (0.952). But the calculated slope of the regression line, 0.53, deviates significantly from integer 1, because the Sangui assay excludes trisialo isotransferrin, resulting in predictably lower values. When the Sangui results were multiplied by the ratio of the cutoffs for alcohol abuse (Predicate Device ÷ Proposed Device, i.e. 6.0 ÷ 2.7), linear regression analysis gave a slope of 1.18, without affecting the Pearson's R. Two (2) additional methods of correlation were studied to illustrate the high degree of correlation:

- (1) Passing Bablok statistical algorithm, a statistical method deemed more accurate than linear regression by most Western Europeans.
- (2) Graphical analysis of the data via the use of a scattergraph.

Performance characteristics were compared to the predicate device. Additional clinical data was submitted to substantiate the advantages of the enhanced diagnostic sensitivity and efficiency, resulting from the exclusion of trisialo isotransferrin in the proposed device

Thus, the safety of effectiveness of the device is confirmed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

AUG 23 2000

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

John J. Kiang, M.S.  
Business and Product Development Consultant  
Sangui BioTech, Inc.  
1508 Brookhollow Drive  
Suite 354  
Santa Ana, California 92705

Re: K001943  
Trade Name: ChronAlco I.D.™ CDT (Carbohydrate Deficient Transferrin) Assay  
Regulatory Class: I  
Product Code: NAO  
Dated: June 20, 2000  
Received: June 26, 2000

Dear Mr. Kiang:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895.

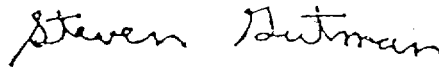
A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in cursive script that reads "Steven Gutman".

Steven I. Gutman, M.D., M.B.A.  
Director  
Division of Clinical Laboratory Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

**Section 6c:**

**Statement of Indications for Use**

**510 (k) Number:** K001943

**Device Name:**

Sangui BioTech, Inc. ChronAlco I.D.™ CDT (Carbohydrate Deficient Transferrin) Assay

**Indications For Use:**

The intended use of this product is the quantitative measurement of CDT (Carbohydrate Deficient Transferrin) in human serum. The ChronAlco I.D.™ CDT Test measures the CDT simultaneously with the total transferrin so that the result can be expressed as a relative ratio, i.e. %CDT. %CDT is used as a tool to identify possible chronic heavy alcohol consumption, which is indicated by %CDT values above the cutoff level of 2.7%.

\_\_\_\_\_  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number \_\_\_\_\_

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NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

\_\_\_\_\_  
(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K001943

Prescription Use ☒  
(Per 21 CFR 801.109)

OR

Over-The Counter Use \_\_\_\_\_

(Optional Format 1-2-96)